REMARKS/ARGUMENTS

Claims 1-29 are pending. The proposed amendment amends claims 1, 7, 12, 18 and 23 and cancels claims 4-6, 13, 16 and 17. Support for the amendment can be found throughout the specification and at least at page 5 lines 9-19 and the originally filed claims. Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

35 U.S.C. §102 Rejections

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the . . . claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Thus, to warrant the §102 rejection, the references cited by the Examiner must show each and every limitation of the claims in complete detail. The Applicant respectfully asserts that the cited references fail to do so.

A. Claims 1, 2, 4, 8, 12-14, and 19 have been rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,471,980 to Sirhan, *et al.* (the *Sirhan* patent).

The Applicants respectfully assert that the *Sirhan* patent fails to disclose, teach, or suggest:

> A system for treating a vascular condition, comprising a catheter; and a coated stent operably coupled to the catheter, the coated stent including a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent and a plurality of timing coatings disposed on the distal and proximal ends of the stent, the timing coatings alternating with the therapeutic coatings, wherein each therapeutic coating comprises a bioerodable polymer and a therapeutic agent and wherein each timing coating comprises a bioerodable polymer, wherein each of the plurality of

therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially upon the erosion of the overlying timing coating to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1; or

A coated stent, comprising a stent framework; a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent framework, each therapeutic coating comprising a bioerodable polymer and a therapeutic agent; and a plurality of timing coatings disposed on the distal and proximal ends of the stent framework, the timing coatings alternating with the therapeutic coatings, each timing coating comprising a bioerodable polymer wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

At most, the *Sirhan* patent discloses a scaffold with a polymer matrix 20 that may degrade by bulk degradation, in which the matrix degrades throughout, or preferably by surface degradation, in which only a surface of the matrix degrades over time while maintaining bulk integrity. Alternatively, the matrix 20 may be composed of a nondegradable material which releases mycophenolic acid by diffusion. The matrix 20 may comprise multiple layers 24 and 26, each layer containing mycophenolic acid, a different substance, or no substance. Additionally, the present invention may employ a rate limiting barrier 28 formed between the scaffold 10 and the matrix 20, as illustrated in FIG. 8, or may optionally be formed over the matrix 20. Such rate limiting barriers 28 may be nonerodible and control the flow rate of release by diffusion of the mycophenolic acid 22 through the barrier 28. *See* column 11, lines 32-52. The prosthesis may be coated with a rate limiting barrier or nondegradable matrix having a sufficient thickness to allow diffusion of the mycophenolic acid through the barrier or nondegradable matrix. The prosthesis is implanted in a body lumen so that substantial mycophenolic acid release from the barrier or nondegradable matrix begins after a preselected time period. *See* column 12, lines 14-21.

Both the matrix layers and the rate limiting barrier layers disclosed in the *Sirhan* patent allow diffusion of drug through the layers. The *Sirhan* patent fails to disclose timing layers that

comprise a bioerodable polymer and also therapeutic coatings comprising a bioerodable polymer. Furthermore, the *Sirhan* patent fails to disclose the therapeutic agents being released sequentially, i.e., the therapeutic agents being released one after another. In *Sirhan*, by teaching only rate limiting barriers, and not bioerodable timing coatings, a therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially. Thus, the *Sirhan* patent fails to disclose timing coatings for the sequential release of multiple drugs as claimed.

Claims 2, and 8, and claims 14, and 19 depend directly from independent claims 1 and 12, respectively, and so include all the elements and limitations of their respective independent claims. Claims 4 and 13 have been cancelled. The Applicant therefore respectfully submits that dependent claims 2, 8, 14, and 19 are allowable over the *Sirhan* patent for at least the same reasons as set forth above for their respective independent claims.

Withdrawal of the rejection of claims 1, 2, 4, 8, 12-14, and 19 under 35 U.S.C. §102(b) as being anticipated by the *Sirhan* patent is respectfully requested.

35 U.S.C. §103 Rejections

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.,* 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

B. Claims 1-4, 10-15, and 21-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0033007 to Sirhan, *et al*. (the *Sirhan* B publication) in view of the *Sirhan* patent.

The Applicant respectfully asserts that the *Sirhan* B publication and the *Sirhan* patent, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a).

As discussed in Section A above, the Applicant asserts that the *Sirhan* patent fails to disclose, teach, or suggest:

> A system for treating a vascular condition, comprising a catheter; and a coated stent operably coupled to the catheter, the coated stent including a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent and a plurality of timing coatings disposed on the distal and proximal ends of the stent, the timing coatings alternating with the therapeutic coatings, wherein each therapeutic coating comprises a bioerodable polymer and a therapeutic agent and wherein each timing coating comprises a bioerodable polymer, wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially upon the erosion of the overlying timing coating to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1; or
>
> A coated stent, comprising a stent framework; a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent framework, each therapeutic coating comprising a bioerodable polymer and a therapeutic agent; and a plurality of timing coatings disposed on the distal and proximal ends of the stent framework, the timing coatings alternating with the therapeutic coatings, each timing coating comprising a bioerodable polymer wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

The *Sirhan* B publication also fails to disclose these limitations.

Claims 2, 3, 10, and 11, and claims 14, 15, and 21-22 depend directly or indirectly from independent claims 1 and 12, respectively, and so include all the elements and limitations of their respective independent claims. Claims 4 and 13 have been cancelled. The Applicant therefore respectfully submits that dependent claims 2, 3, 10, 11, 14, 15, and 21-22 are allowable over the *Sirhan* B publication and the *Sirhan* patent for at least the same reasons as set forth above for their respective independent claims.

Withdrawal of the rejection of claims 1-4, 10-15, and 21-22 under 35 U.S.C. §103(a) as

being unpatentable over the *Sirhan* B publication in view of the *Sirhan* patent is respectfully requested.

C. Claims 12-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2003/0153983 to Miller, *et al.* (the *Miller* publication).

The Applicant respectfully asserts that the *Miller* publication fails to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication fails to disclose, teach, or suggest:

> A coated stent, comprising a stent framework; a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent framework, each therapeutic coating comprising a bioerodable polymer and a therapeutic agent; and a plurality of timing coatings disposed on the distal and proximal ends of the stent framework, the timing coatings alternating with the therapeutic coatings, each timing coating comprising a bioerodable polymer wherein a plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 12.

At most, the *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more barrier layers. *See* paragraph [0052]. The *Miller* publication fails to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062].

A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic

agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers. The *Miller* publication does not teach that the barrier layers are bioerodable or that the therapeutic coating has a bioerodable polymer. Therefore, since the *Miller* publication only teaches diffusion of a therapeutic agent through barrier layers, the *Miller* publication does not teach that the therapeutic agents are released sequentially as claimed. In the *Miller* publication, a therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

Claims 14, 15 and 18-20 depend directly or indirectly from independent claim 12, and so include all the elements and limitations of independent claim 12. Claims 13, 16 and 17 have been cancelled. The Applicant therefore respectfully submits that dependent claims 14, 15 and 18-20 are allowable over the *Miller* publication for at least the same reasons as set forth above for independent claim 12.

Withdrawal of the rejection of claims 12-20 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication is respectfully requested.

D. Claims 1-3 and 5-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan* B publication.

The Applicant respectfully asserts that the *Miller* publication and *Sirhan* B publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication fails to disclose, teach, or suggest:

> A system for treating a vascular condition, comprising a catheter; and a coated stent operably coupled to the catheter, the coated stent including a plurality of therapeutic coatings disposed on a distal end and a proximal end of the stent and a plurality of timing coatings disposed on the distal and proximal ends of the stent, the

timing coatings alternating with the therapeutic coatings, wherein each therapeutic coating comprises a bioerodable polymer and a therapeutic agent and wherein each timing coating comprises a bioerodable polymer, wherein each of the plurality of therapeutic agents is released from the plurality of therapeutic coatings, the therapeutic agents being released sequentially upon the erosion of the overlying timing coating to inhibit restenosis adjacent to the ends of the stent, as recited in independent claim 1. The *Sirhan* B publication also fails to disclose these limitations.

The *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more barrier layers. *See* paragraph [0052]. The *Miller* publication fails to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062].

A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers. The *Miller* publication does not teach that the barrier layers are bioerodable or that the therapeutic coating has a bioerodable polymer. Therefore, since the *Miller* publication only teaches diffusion of a therapeutic agent through barrier layers, the *Miller* publication does not teach that the therapeutic agents are released sequentially as claimed. In the *Miller* publication, a therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer

layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

Claims 2-3 and 7-9 depend directly or indirectly from independent claim 1 and so include all the elements and limitations of independent claim 1. Claims 5 and 6 have been cancelled. The Applicant therefore respectfully submits that dependent claims 2-3 and 7-9 are allowable over the *Sirhan* B publication and the *Sirhan* patent for at least the same reasons as set forth above for their respective independent claims.

Withdrawal of the rejection of claims 1-3 and 5-9 under 35 U.S.C. §103(a) as being unpatentable over the *Miller* publication in view of the *Sirhan* B publication is respectfully requested.

E. Claims 23-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the *Sirhan* B publication in view of the *Miller* publication.

The Applicant respectfully asserts that the *Sirhan* B publication and the *Miller* publication, alone or in combination, fail to disclose, teach, or suggest each and every element of the Applicant's invention as claimed, as required to maintain a rejection under 35 U.S.C. §103(a). The Applicant asserts that the *Miller* publication fails to disclose, teach, or suggest:

> A method of inhibiting restenosis adjacent to the ends of a stent used to treat a vascular condition, comprising: providing a coated stent, the coated stent including a first and a second therapeutic coating disposed on a distal and a proximal end of the stent, the first therapeutic coating including a bioerodable polymer and a first therapeutic agent, the second therapeutic coating including a second therapeutic agent, the coated stent further including a first timing coating positioned between the first and second therapeutic coatings, the timing coating comprising a bioerodable polymer; deploying the coated stent in a vessel; releasing the first therapeutic agent from the first therapeutic coating; eroding the bioerodable polymer of the first therapeutic coating; actuating the first timing coating based on the eroding of the bioerodable polymer; and releasing the second therapeutic agent from the second therapeutic coating at a time controlled by the first timing coating, as recited in independent claim 23.

The *Sirhan* B publication also fails to disclose these limitations.

At most, the *Miller* publication discloses a medical device may comprise one or more layers comprising one or more distinct matrix polymer layers and, if desired, one or more barrier layers. *See* paragraph [0052]. The *Miller* publication fails to disclose a timing coating as claimed. At most, the *Miller* publication discloses a barrier layer allowing diffusion through the barrier layer. *See* paragraph [0062].

A barrier layer can be provided to control the rate of release of bioactive material or therapeutic agent from an adjacent layer, such a matrix polymer layer. *See* paragraph [0055]. First and second barrier layers (also annular in shape) are disposed on the exterior and interior surfaces, respectively, of the first annular layer. The first and second barrier layers that enclose the first annular layer are typically less permeable than the biocompatible matrix polymer and, thereby, control the rate of diffusion of the bioactive and optional therapeutic agents from the device to the external environment. *See* paragraph [0056]. The bioactive and/or therapeutic agent from the annular layer comprising the first matrix polymer composition would have to diffuse through its own barrier layer, into and through an annular layer comprising the second matrix polymer composition and through another barrier layer before reaching the external environment. *See* paragraph [0062]. Thus, the barrier layers of the *Miller* publication allow diffusion of the therapeutic agents through the barrier layers. The *Miller* publication does not teach that the barrier layers are bioerodable or that the therapeutic coating has a bioerodable polymer. Therefore, since the *Miller* publication only teaches diffusion of a therapeutic agent through barrier layers, the *Miller* publication does not teach eroding the bioerodable polymer of the first therapeutic coating; actuating the first timing coating based on the eroding of the bioerodable polymer and releasing the second therapeutic agent from the second therapeutic coating at a time controlled by the first timing coating, as claimed. In the *Miller* publication, a therapeutic agent from an inner layer will diffuse through the outer layers and mix with therapeutic agents from the outer layers, so that the inner and outer layer drugs are administered simultaneously rather than sequentially.

Claims 24-29 depend directly or indirectly from independent claim 23, and so include all the elements and limitations of independent claim 23. The Applicant therefore respectfully

submits that dependent claims 24-29 are allowable over the *Sirhan* B publication in view of the *Miller* publication for at least the same reasons as set forth above for independent claim 23.

Withdrawal of the rejection of claims 23-29 under 35 U.S.C. §103(a) as being unpatentable over the *Sirhan* B publication in view of the *Miller* publication is respectfully requested.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,
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